

## CTMS Structured Protocol Representation SIG Teleconference Meeting Minutes

Meeting Date	Tuesday, October 5, 2004																																																																				
	1-2 PM EDT																																																																				
Attendees:	<b>Working group coordinators:</b> Scott Finley (Booz Allen Hamilton), Harshawardhan Bal (Booz Allen Hamilton)																																																																				
	<b>Participants:</b>																																																																				
	<table><tr><th>Name</th><th>Email</th><th>Center</th></tr><tr><td>Andrea Hwang</td><td>ychwang@uci.edu</td><td>UC Irvine</td></tr><tr><td>Angela Howard</td><td>Angela.Howard@stjude.org</td><td>St. Jude Children's Research Hospital</td></tr><tr><td>Beverly Meadows</td><td>meadowsb@ctep.nci.nih.gov</td><td>CTEP</td></tr><tr><td>Brenda Crocker</td><td>crockerbl@upmc.edu</td><td>UPMC</td></tr><tr><td>Christo Andonyadis</td><td>andonyac@mail.nih.gov</td><td>NCI</td></tr><tr><td>Doug Fridsma</td><td>fridsma@cbmi.pitt.edu</td><td>UPMC</td></tr><tr><td>Harshawardhan Bal</td><td>bal_harshawardhan@bah.com</td><td>BAH</td></tr><tr><td>John Speakman</td><td>speakman@biost.mskcc.org</td><td>Sloan-Kettering</td></tr><tr><td>Joyce Niland</td><td>jiland@coh.org</td><td>City of Hope</td></tr><tr><td></td><td></td><td>Cancer Information Products and Systems, NIH</td></tr><tr><td>Lakshmi Grama</td><td>lgrama@mail.nih.gov</td><td>NIH</td></tr><tr><td>Linda Schmandt</td><td>lms@pitt.edu</td><td>UPMC</td></tr><tr><td>Lori Wangsness</td><td>wangsness.lori@mayo.edu</td><td>Mayo</td></tr><tr><td></td><td></td><td>University of Nebraska Medical Center</td></tr><tr><td>Marsha Ketcham</td><td>mketcham@unmc.edu</td><td>University of Nebraska Medical Center</td></tr><tr><td>Oleg Shats</td><td>oshats@unmc.edu</td><td>University of Nebraska Medical Center</td></tr><tr><td>Rebecca Boes</td><td>boesr@msx.upmc.edu</td><td>UPMC</td></tr><tr><td>Robert Morrell</td><td>bmorrell@wfubmc.edu</td><td>Wake Forest CCC</td></tr><tr><td>Scott Finley</td><td>Finley_scott@bah.com</td><td>BAH</td></tr><tr><td>Sharon Elcombe</td><td>elcombe@mayo.edu</td><td>Mayo</td></tr><tr><td>Smita Hastak</td><td>hastaks@mail.nih.gov</td><td>NCI</td></tr></table>			Name	Email	Center	Andrea Hwang	ychwang@uci.edu	UC Irvine	Angela Howard	Angela.Howard@stjude.org	St. Jude Children's Research Hospital	Beverly Meadows	meadowsb@ctep.nci.nih.gov	CTEP	Brenda Crocker	crockerbl@upmc.edu	UPMC	Christo Andonyadis	andonyac@mail.nih.gov	NCI	Doug Fridsma	fridsma@cbmi.pitt.edu	UPMC	Harshawardhan Bal	bal_harshawardhan@bah.com	BAH	John Speakman	speakman@biost.mskcc.org	Sloan-Kettering	Joyce Niland	jiland@coh.org	City of Hope			Cancer Information Products and Systems, NIH	Lakshmi Grama	lgrama@mail.nih.gov	NIH	Linda Schmandt	lms@pitt.edu	UPMC	Lori Wangsness	wangsness.lori@mayo.edu	Mayo			University of Nebraska Medical Center	Marsha Ketcham	mketcham@unmc.edu	University of Nebraska Medical Center	Oleg Shats	oshats@unmc.edu	University of Nebraska Medical Center	Rebecca Boes	boesr@msx.upmc.edu	UPMC	Robert Morrell	bmorrell@wfubmc.edu	Wake Forest CCC	Scott Finley	Finley_scott@bah.com	BAH	Sharon Elcombe	elcombe@mayo.edu	Mayo	Smita Hastak	hastaks@mail.nih.gov	NCI
	Name	Email	Center																																																																		
	Andrea Hwang	ychwang@uci.edu	UC Irvine																																																																		
	Angela Howard	Angela.Howard@stjude.org	St. Jude Children's Research Hospital																																																																		
	Beverly Meadows	meadowsb@ctep.nci.nih.gov	CTEP																																																																		
	Brenda Crocker	crockerbl@upmc.edu	UPMC																																																																		
	Christo Andonyadis	andonyac@mail.nih.gov	NCI																																																																		
	Doug Fridsma	fridsma@cbmi.pitt.edu	UPMC																																																																		
	Harshawardhan Bal	bal_harshawardhan@bah.com	BAH																																																																		
	John Speakman	speakman@biost.mskcc.org	Sloan-Kettering																																																																		
	Joyce Niland	jiland@coh.org	City of Hope																																																																		
			Cancer Information Products and Systems, NIH																																																																		
	Lakshmi Grama	lgrama@mail.nih.gov	NIH																																																																		
	Linda Schmandt	lms@pitt.edu	UPMC																																																																		
	Lori Wangsness	wangsness.lori@mayo.edu	Mayo																																																																		
			University of Nebraska Medical Center																																																																		
	Marsha Ketcham	mketcham@unmc.edu	University of Nebraska Medical Center																																																																		
	Oleg Shats	oshats@unmc.edu	University of Nebraska Medical Center																																																																		
	Rebecca Boes	boesr@msx.upmc.edu	UPMC																																																																		
	Robert Morrell	bmorrell@wfubmc.edu	Wake Forest CCC																																																																		
	Scott Finley	Finley_scott@bah.com	BAH																																																																		
	Sharon Elcombe	elcombe@mayo.edu	Mayo																																																																		
	Smita Hastak	hastaks@mail.nih.gov	NCI																																																																		
	Agenda																																																																				
		1. Approval of minutes																																																																			

The minutes of the September 2, 2004 teleconference were approved.

## **2. Review of Action Items from last meeting**

**Coordinate with Joyce Niland and Andrea Hwang for deriving use cases based on the NCI Summary 4 document:** Joyce, Andrea, Doug and Todd Thornburgh from Wake Forest reviewed this and agreed on an agenda for user requirements gathering. Around the time of the workspace face-to-face meeting in November they will do this with City of Hope and UCI and use the results as a model for other places. Doug will send Scott some comments on this topic.

**Obtain list of individuals from cooperative groups and Pharma companies (from Becky Kush, CDISC) for Protocol authoring tool user requirements gathering:** We don't have such a list but Doug has been encouraging as much CDISC participation as possible in caBIG. Becky will give a presentation at the face-to-face meeting. As far as the cooperative groups are concerned, next week there is a meeting in Philadelphia of the CTSU (Clinical Trials Support Unit) who provide central IT support for the cooperative groups; Sue Dubman will speak, and Scott and Sharon will attend. Scott and Sharon will report back to the next teleconference on the meeting, especially in terms of identifying key contacts and stakeholders in the CTSU who can help us integrate our work, specifically our protocol representation model, with theirs.

**Send suggestions for agenda items to Scott Finley for the November CTMS face-to-face meeting at City of Hope:** Suggestions were received; Scott has written and circulated a draft of the agenda.

**Work with Bob Morrell to create a white paper on Summary Three and Four reports:** Doug and Bob had intensive discussions on this topic. The result was a feeling that because so much of the data on these summary reports is aggregated or computed data, it doesn't really make sense to make them an integral part of the representation of a protocol. We would like to represent the essential elements, rather than aggregated or computed values, in the database. Furthermore, Scott observed that because Summary 4 has a regulatory component, there is sensitivity that any attempts to influence it may be misconstrued as an attempt to influence regulation. Joyce reported that, as requested at the previous teleconference, she spoke with Linda Weiss who oversees Summary 4 reporting at NCI, will have a discussion with Ken Buetow about this. Sharon raised the issue that a new Summary 4 specification, with significant differences from the existing Summary 4, has just been released by NCI. The group felt that this was another reason not to tie effort around Summary 4 at this stage.

The group discussed whether a better way to start might be to take a

step back and identify the essential elements in identifying a protocol, such as (for instance) eligibility criteria. Doug made the comment that the advantage of Summary 4 as a use case was that it forces us to interact with the Common Data Elements in the NCI's caDSR. The vocabulary standards for eligibility criteria are not there yet in the caDSR. The consensus seemed to be that even eligibility criteria were not fundamental enough and we should focus on identifying a core set of data elements that might be needed to identify a protocol, and indeed to uniquely identify an institution, in a federated and reliable way.

This would imply that in the first round we would not create an application to generate Summary 4 reports in the first round of development, but create an underlying infrastructure that would allow a Summary 4 application to be created in the second round, which could maybe involve the development of a Summary 4 message which could be submitted to HL7.

Doug made the observation that maybe 70-80% of the core data elements will overlap with those required for adverse event reporting, so this must be a collaborative effort.

A decision was made to focus the pilot on (1) identifying the core elements needed to define a protocol and (2) developing a methodology for uniquely identifying an institution. Bev informed the group that CTEP have been working with the CTSU and others to improve and refine the list of institution codes (formerly the CTEP IDs and/or NCI IDs) that we should look at before we reinvent the wheel. Bev further commented that as CDISC already has a spreadsheet list of data elements as part of their Protocol Representation effort, this group should review those first. John agreed to circulate this to the group.

Doug will prepare a documented description of how we plan to move forward and circulate it to the group for comments before the next meeting. Scott observed that we have to at least state the long term goals, the use case, as well. Bob identified the use case as a universal registry of clinical trials to which centers would have to publish details of all trials. Any comments on this direction should be sent to Doug as soon as possible.

### **3. Review of Summary 4 analysis**

Already covered above.

### **4. Discussion of SPR Protocol Authoring scope**

Likewise also covered.

### **5. Comments regarding face-to-face meeting agenda**

	<p>Already covered in the discussion of the action items from the last teleconference. However, further comments are still welcome and should be sent to Scott. Scott made the observation that if individuals want to suggest new activities at the meeting, it would be helpful to also indicate what existing activities on the agenda might be eliminated or curtailed to make space for them.</p> <p><b>6. Walk-ins</b></p> <p>One item not covered in the published agenda was raised. Doug noted that at the upcoming caBIG joint Architecture and VCDE Workspaces face-to-face meeting in Chicago that use cases from the Clinical Trials Workspace will be discussed. We were not aware that we had supplied any use cases for discussion. John, who will attend the meeting, will take this up with Arumani Manisundaram before the meeting.</p>
<p><b>Next meetings</b></p>	<p><b>Next teleconference: Nov 2nd</b>  <b>Face to face meeting Nov 16th</b></p>
<p><b>Action items</b></p>	<ul style="list-style-type: none"> <li>• Doug will send some comments to Scott on the topic of use cases.</li> <li>• Scott and Sharon will report back to the next teleconference on the CTSU meeting, especially in terms of identifying key contacts and stakeholders.</li> <li>• John will circulate to the group CDISC's spreadsheet of Protocol Representation data elements.</li> <li>• Doug will prepare a documented description of how we plan to move forward and circulate it to the group for comments before the next meeting.</li> <li>• John will take up the question of use cases for the Architecture Workspace face-to-face meeting with Arumani Manisundaram.</li> </ul>